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Date: June 30, 2008

By //Kurt G. Briscoe//
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Attorney Docket No. 107101-10

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT	:	Johannes BARTHOLOMAUS, et al
SERIAL NO.	:	10/718,112
CUSTOMER NO.	:	27384
FILED	:	November 20, 2003
FOR	:	ABUSE-PROOFED DOSAGE FORM
ART UNIT	:	1618
EXAMINER	:	MELISSA JEAN PERREIRA

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT OF SUBSTANCE OF INTERVIEW

SIR:

An interview was held in connection with this application on May 29, 2008. Applicants herein report the substance of such interview.

During the single interview, four different applications were discussed, for the most part as a single group as common issues were involved in all four applications. The applications were: USSNs 10/718,112; 10/890,704; 11/349,544; and 11/462,216.

In attendance were Examiner Dameron Jones, Examiner Melissa Perreira and the undersigned.

A brief general discussion was had about the form of certain of the claims. Referring to claim 1 of USSN 11/349,544, the Examiners suggested that, for purposes of clarity, the various components be broken out into a numbered-list or lettered-list with each component on a separate line.

With respect to claim 28 of the same application, the Examiners questioned the correctness of starting the lettered-list with the letter "z" and then lettering the subsequent items in the list "y" then "x" then "w." According to the Examiners, it was unclear whether the process was intended to start with item "z" or with "w" or earlier on with unspecified "a."

Turning to the merits of the substantive rejections of record, the undersigned argued that the claims were not anticipated by or obvious over any of the prior art of record because the claims required that the dosage form have "a breaking strength of at least 500 N" and this was not expressly taught by the cited prior art taken either alone or in combination and, moreover, was not inherent, as demonstrated by the Bartholomaus Declaration that had been filed in USSNs 10/890,704, 11/349,544 and 11/462,216. The undersigned urged that the Bartholomaus Declaration showed that simply because the cited prior art taught the use of materials that were the same as those useful in the present invention did not necessarily mean that the dosage forms obtained in the prior art or following the teachings of the prior art had or would have had a breaking strength of 500 N, as required by the instant claims. Indeed, Examples 1 and 2 are reproductions of examples of Oshlack, US 2003/0064099, relied on primarily by the Examiners. As shown in the Bartholomaus Declaration, neither one of these examples achieved a breaking strength of at least 500 N as required by the present claims. Instead, the breaking strengths achieved in the two reproduced Oshlack examples were much lower, being in the range of "chewable" materials, which is consistent with Oshlack's own teachings that his dosage forms are chewable.

The undersigned urged that in the absence of an express teaching that the prior art dosage forms have a breaking strength of at least 500 N, and since Applicants have shown that a breaking strength of at least 500 N is not inherent in the prior art materials, the limitation in the instant claims of "a breaking strength of at least 500 N" was not met by the cited prior art and would not have been obvious over the cited prior art and, therefore, all of the prior art rejections needed to be reconsidered and withdrawn.

The Examiners did not completely agree with this point, arguing that because the claimed dosage forms are made from the same materials as the prior art dosage forms, the two dosage forms must have identical properties.

The undersigned argued that this presumption of identical properties only applies where two materials are, in fact, identical. Further, in many cases, such as the present case, identity as to materials is not determined solely by the ingredients used to make the respective materials, but also by the manner in which the materials are formed. It was well known in the this art, as supported by the Examiners' own reference to the Maggi article, of record, that the compression force applied to the ingredients could have an effect on the properties, specifically, the hardness, of the resulting dosage form obtained. Under these circumstances, the undersigned continued, there was no justification for continuing with the obviously inapplicable principle that because the same materials were used, the resulting dosage forms must have identical properties. This was clearly not true and, moreover, the Examiners' own evidence proved this was not true.

The Examiners pointed out that at the very least Maggi taught that compression force was a result-effective variable with respect to hardness and, therefore, it would have been obvious to optimize hardness. The undersigned disagreed, pointing out that what was missing in the combination of references was any teaching or suggestion that the dosage form should be made so hard as to have a breaking strength of at least 500 N, as required by the instant claims, to thereby be so hard that the dosage from cannot be crushed, for example, with a hammer, as demonstrated in the instant examples. The undersigned urged the Examiners to consider that an important aspect of the present invention is the ***idea*** that a dosage form having the hardness

required by the instant claims is of some advantage, in this case, in proofing the dosage form against drug abuse. If that idea could be found in the cited combination of references, then the Examiner's case would be colorable, but in the absence of that concept in the cited combination of references, there was no apparent reason on the record why someone should chose the necessary ingredients from the primary references, especially Oshlack 2003/0064099, and then formulate them into a dosage form having the unusually high breaking strength of at least 500 N, as required by the instant claims.

The Examiners agreed to reconsider this point whether there really was a teaching or suggestion and motivation in the cited references to make a dosage form having a breaking strength of at least 500 N.

The Examiners then pointed out that even if that issue was decided in Applicants' favor, the evidence was not commensurate in scope with the claims. They pointed out that page 6 of the Bartholomaus Declaration established certain criteria as being critical to the results obtained, namely the chemical nature of component (C), the molecular weight of component (C) and the amount of component (C), but these criteria were not specified in the claims. The undersigned attempted to argue that these were only some of the choices that had to be made within Oshlack's disclosure to arrive at the instant dosage forms, and there was no guidance in Oshlack to make these choices, thereby supporting Applicants' case that Oshlack did not teach or suggest the present invention. The undersigned stated his personal belief that Dr. Bartholomaus did not mean that only these materials, molecular weights and amounts were useful. The Examiners did not agree with this view.

The undersigned agreed to discuss the new points raised by the Examiners with the client and to file a further paper addressing them, and also to file original Bartholomaus Declarations in the respective cases. (The undersigned had filed a copy of the Bartholomaus Declaration from one case in another case.)

The foregoing is believed to be a complete and accurate statement of the substance the

interview.

Respectfully submitted,

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